UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE OPINIONS OF RON NAJAFI, PH.D.

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Pursuant to Federal Rules of Evidence 702 and 703, Defendants' Executive Committee, on behalf of all Defendants in this litigation, submits this Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Dr. Ron Najafi ("Motion").

INTRODUCTION

Ron Najafi—a chemist and owner of the laboratory Emery Pharma—submitted a seven-page declaration setting forth his opinion that valsartan medication that purportedly contained any level of NDMA and/or NDEA is not "the same and/or the chemical equivalent" of the reference listed drugs, Diovan or Exforge (collectively, "RLDs"). Dr. Najafi also offers opinions, without meaningful analysis, regarding the alleged carcinogenicity of NDMA and NDEA and Defendants' purported manufacturing obligations.

The Court should exclude Dr. Najafi's novel theory that Defendants' VCDs are not the same as the RLDs for two reasons. ***First***, Dr. Najafi's sameness opinion goes well beyond established regulatory standards governing sameness. Instead, Dr. Najafi attempts to graft a new theory of his own creation onto the FDA sameness requirement. Notably, his "chemical equivalence" requirement is not defined or recognized by any regulatory agency, including the FDA; nor is it recognized in the scientific community. The relevant sameness inquiry is whether Defendants' VCDs were bioequivalent to the RLDs, and it is beyond dispute—**as reflected by Dr.**

Najafi's own testimony—that Defendants' VCDs met this requirement. Thus, Dr. Najafi's sameness opinion is so divorced from the law and the facts that it lacks even a scintilla of relevance to class certification, and should be excluded.

Second, Dr. Najafi's theory is premised on a flawed assumption that is easily debunked, rendering his methodology unreliable. Dr. Najafi assumes that the RLDs did not contain nitrosamines, and, as a result, that VCDs that contain any level of a nitrosamine are not "the same." In fact, there is evidence that some lots of the RLDs did, in fact, contain detectable levels of NDMA. And if the RLDs contained detectable levels of NDMA, then Defendants' VCDs could not have violated Dr. Najafi's fabricated sameness requirement.

Dr. Najafi's remaining opinions concern liability issues related to the Defendants' manufacturing practices. These conclusions—which constitute pure legal argument—do not fall within his areas of expertise, are not supported by meaningful analysis and, again, have no bearing on class certification. As a result, these opinions would not be helpful to the finder of fact and fail to satisfy *Daubert*'s "fit" requirement.

For all of these reasons, discussed further below, the Court should exclude Dr. Najafi's proffered opinions in their entirety.

BACKGROUND[1]

Dr. Najafi is a chemist with a Ph.D. in Organic Chemistry and the owner and CEO of Emery Pharma, a research laboratory. Ex. A, Declaration of Ron Najafi ("Najafi Rep.") ¶¶ 6, 10, Nov. 4, 2021. Dr. Najafi is not a medical doctor, a toxicologist, or an epidemiologist and has never done any peer-reviewed research on the carcinogenicity of NDMA. Ex. B, Deposition of Ron Najafi ("Najafi Dep.") 106:5-106:18, Feb. 3, 2022. Dr. Najafi has offered the following opinions in an attempt to support Plaintiffs' motion for class certification:

- "Valsartan containing products that contained NDMA and NDEA were not the generic equivalent of Diovan or Exforge because they contained NDMA and NDEA." Najafi Rep. ¶ 32.
- "[T]he Valsartan containing products with NDMA and NDEA were not the same as or chemically equivalent to the brand name Diovan or Exforge products because they contained NDMA and NDEA." *Id.* ¶ 33.
- "NDMA and NDEA are carcinogenic and should not be present in any drugs." *Id.* ¶ 30.

[1] Defendants have filed a Motion to Compel related to certain documents in Dr. Najafi's possession concerning his testing of VCDs, which Plaintiffs have refused to produce. Dkt. 2013. To the extent the Court grants Defendants' Motion to Compel, additional grounds to exclude Dr. Najafi's unreliable opinions may become known. Accordingly, Defendants reserve the right to move to exclude or limit Dr. Najafi's opinions on grounds other than those set forth herein.

- "Defendants had an obligation to manufacture their products in such a way that they could assure the identity, strength, quality, and purity of their Valsartan containing products and could assure that their Valsartan containing products did not contain NDMA or NDEA." *Id.* ¶ 31.

Dr. Najafi testified that he has not tested either Diovan or Exforge to determine whether they contain any level of NDMA or NDEA. Najafi Dep. 138:4-138:13.[2] Instead, he assumed for purposes of his report that the Novartis products did not contain NDMA or NDEA at any level above zero. *Id.* 139:24-140:7.

LEGAL STANDARD

Defendants incorporate by reference the Legal Standard set forth in the Memorandum of Law in Support of Defendants' Motion to Exclude Opinions of Edward Kaplan, M.D.

ARGUMENT

I. DR. NAJAFI'S SAMENESS OPINION IS UNRELIABLE AND IRRELEVANT.

Dr. Najafi's central opinion is that generic VCDs that contained NDMA or

[2] As discussed further below, Dr. Najafi disclosed at his deposition that his company, Emery Pharma, has tested samples of VCDs for NDMA levels in connection with a citizen petition that was submitted to FDA by Valisure LLC. Najafi Dep. 115:17-116:24; *see also* Ex. C, Valisure Cit. Pet. Dr. Najafi testified that he is not aware of which companies' VCDs were tested by his company, Najafi Dep. 117:18-20, and Plaintiffs have refused to produce records related to that testing. *See* Dkt. 203.

NDEA at any level were not the same as and/or "chemically equivalent to" Novartis's RLDs, Diovan and Exforge. Najafi Rep. ¶ 33. This opinion is invalid on its face because Dr. Najafi's "chemical equivalence" test is not part of the regulatory sameness standard for generic drugs. Rather, he invented a requirement that is found nowhere in Title 21, the regulations, or FDA's guidance, and is not recognized by the scientific community. Simply put: Defendants could not have violated this test because it does not exist. This renders Dr. Najafi's opinion irrelevant and unreliable.

Dr. Najafi's sameness opinion is also unreliable because it is predicated on the core assumption that all of Defendants' VCDs contained NDMA or NDEA at some level above zero, and that the RLDs did not contain NDMA or NDEA at any level above zero. Najafi Dep. 139:24-140:7. With regard to the RLDs, Dr. Najafi's assumption is demonstrably false;[3] accordingly, his methodology is unreliable and his class certification opinions should be excluded.

A. Generic VCDs are not Required to be the "Chemical Equivalent" of the RLDs.

[3] Not all of Defendants' VCDs contained NDMA or NDEA at detectable levels. Defendant Aurobindo did not detect NDMA in any of its VCD batches, nor did it detect NDEA in all of its VCD batches. Aurobindo therefore only recalled certain batches. *See, e.g.*, Ex. D, APL-MDL 2875-0105101; FDA, *Aurobindo Pharma USA, Inc. Recall Notice*, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-consumer-level-recall-80-lots-amlodipine (last accessed April 25, 2022). Similarly, although Teva did recall all lots with expiry, certain lots of amlodipine valsartan manufactured by Teva using Mylan's API and tested by FDA did not contain detectable levels of NDMA or NDEA. Ex. E, FDA News Release, May 21, 2019 "Laboratory analysis of valsartan products." Thus, both of Dr. Najafi's core assumptions are incorrect.

In order to satisfy Rule 702's "fit" requirement, Dr. Najafi's testimony must "assist the trier of fact to understand the evidence or to determine a fact in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993). "[E]xpert evidence which does not relate to an issue in the case is not helpful." *U.S. v. Ford*, 481 F.3d 215, 220 n.6 (3d Cir. 2007) (quoting *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999)). The "fit" requirement "goes primarily to relevance." *Daubert*, 509 U.S. at 591. Despite Dr. Najafi's assertions, regulatory sameness and "chemical equivalence" are not one and the same. Indeed, whether Defendants' VCDs were chemically equivalent to the RLDs has no bearing on whether the active ingredient(s) in Defendants' VCDs were the same as the RLDs pursuant to FDA's requirements and federal law. Because Dr. Najafi's "chemical equivalence" opinion is untethered from laws and regulations that govern generic pharmaceutical manufacturing, it has no bearing on any fact in this litigation related to class certification. *See, e.g.*, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (1997) (expert testimony properly excluded where "there is simply too great an analytical gap between the data and the opinion proffered").

Notably, "chemical equivalence" does not appear in any federal statute, regulation, or FDA guidance related to generic drugs; "nor is it a phrase used by the scientific community." Ex. F, Supplemental Report of Michael Bottorff ("Bottorff Suppl. Rep.") 43, Jan. 12, 2022; *see also* Najafi Dep. 34:19-35:4 (testifying that he

does not know whether the term "chemical equivalence" appears in the Food, Drug and Cosmetics Act or FDA regulations). Similarly, there is no requirement that generic VCDs have the identical impurity profile as the RLDs. Najafi Dep. 19:6-15 ("The FDA does not require []the generic drug manufacturer to match every impurity of the branded drug."). Essentially, Dr. Najafi has conjured a regulatory standard that no agency applies, and then offered an improper legal conclusion that Defendants' VCDs failed to comply with his imaginary standard. Not only is this preposterous, but it has nothing to do with class certification, and the Court should disregard it.

According to Dr. Najafi, there is no distinction between his "chemical equivalence" theory and the regulatory requirement of sameness. Najafi Dep. 34:19-22 ("Sameness is chemical equivalence."). When confronted, however, Dr. Najafi was unable to support this conclusion with any citation to federal law, regulations or guidelines, *id.* 30:20-33:8; 34:19-37:7, because no such requirement exists. In order to legally manufacture a generic equivalent to a brand name drug, a manufacturer must submit an Abbreviated New Drug Application ("ANDA") to FDA. 21 U.S.C.A. § 355(j). A generic drug manufacturer can only legally sell a medication in the United States after FDA approves its ANDA. 21 U.S.C.A. § 355(a). Federal law requires that an ANDA must contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug

have been previously approved for [the RLD]." 21 U.S.C.A. § 355(j)(2)(A)(i). The ANDA must also contain information showing "**that the active ingredient** of the new drug **is the same** as that of the listed drug." 21 U.S.C.A. § 355(j)(2)(A)(ii) (emphases added). This requirement of sameness between the generic drug and the RLD also applies to the route of administration, dosage form, strength, and labeling. 21 U.S.C.A. § 355(j)(2)(A)(iii), (v). Notably, the only type of "equivalence" required—or even referenced—in Title 21 is bioequivalence. Specifically, an ANDA must contain:

> information to show that the new drug is bioequivalent to the listed drug referred to in clause (i) . . . [or] information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i).

21 U.S.C.A. § 355(j)(2)(A)(iv). Bioequivalence tests whether the generic drug is absorbed at a similar rate and extent as the listed drug, or if there is otherwise a difference between the generic drug and the listed drug in safety and therapeutic effect, not whether the chemical makeup of the generic drug and listed drug is identical. *See* 21 U.S.C.A. § 355(j)(8)(B). There is no reference to "chemical equivalence" anywhere in the statute.

Likewise, nowhere in Title 21 or the regulations is there a requirement that generic drug manufacturers use the same manufacturing process as the RLD. Dr.

Najafi conceded as much:

> Q. Does FDA require the supplier of an active pharmaceutical ingredient used in generic drug to use the same synthetic process used by the [R]LD holder?
>
> MR. NIGH: Form objection.
>
> A. The FDA does not require the generic manufacturers to use exact procedure of the branded drug.
>
> Q. When you say "exact procedure," my question is are they required to use the same synthetic process for developing and producing API. The answer is no, correct?
>
> * * *
>
> A. . . . FDA does not require a generic manufacturer to use exact chemical procedure as the brand to synthesize the generic drug.

Najafi Dep. 18:4-5; 18:21-25.

As Dr. Najafi acknowledged, where a generic manufacture uses a different synthetic process, the impurity profile of the generic drug will necessarily be different from the RLD. Najafi Dep. 19:6-15; *see also* Ex. G, Expert Report of Eric Sheinin ("Sheinin Report") ¶ 94, January 12, 2022 ("Because the synthetic process differs [from that used to manufacture the RLDs] it is quite common for a different set of impurities to be present in the API used in an ANDA, i.e., there can be a different impurity profile.").

Importantly, Dr. Najafi also admitted that bioequivalence does not depend in any way on the impurity profile of the generic drug and the RLDs:

> A. The generic manufacturer can establish bio equivalence or a synthetic process irrespective of whether they have -- [] what kind of impurities they have. They could have harmful impurities, they could have harmless impurities, and they can still establish bio equivalence, but that's irrespective of what kind of impurities they have.

Najafi Dep. 20:18-21:4. This admission is fatal to his theory that the presence of NDMA or NDEA, which Dr. Najafi assumes rendered Defendants' VCDs not "chemically equivalent" to the RLDs, affected the sameness of Defendants' VCDs. Further, because Dr. Najafi admits that generic drugs can remain bioequivalent irrespective of the presence of impurities, and nitrosamines are impurities, Dr. Najafi's litigation standard of sameness necessarily fails.

Dr. Najafi offers no opinion on whether Defendants' VCDs are bioequivalent to the RLDs. Moreover, Dr. Najafi has conceded that he does not know whether the presence of NDMA or NDEA affects the efficacy of blood pressure medication, testifying, "that's for another expert to comment." *Id.* 193:18-19. In fact, "there is no evidence of a pharmaceutical interaction that either NDMA or NDEA would degrade or alter the structure of valsartan in the dosage form prior to administering to a patient; thus, the administered generic valsartan dosage form would contain the 'chemically equivalent' amount of valsartan stated in the approved ANDA." Bottorff Rep. 44. Likewise, there is no pharmacological evidence that the presence of NDMA or NDEA diminishes the efficacy of VCDs. *Id.* ("[T]here is no overlapping or competing mechanism for any of the pharmacologic processes of valsartan or the

nitrosamines, neither pharmacodynamic nor pharmacokinetic."). Dr. Najafi offers no methodology or testing to contradict this.

Even if Dr. Najafi's "chemical equivalence" theory was embodied in the law—and it is not—the Court should still exclude his testimony because it constitutes an improper legal opinion regarding the sameness requirements under the Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations. *See Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) ("Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that embraces an ultimate issue to be decided by the trier of fact, an expert witness is prohibited from rendering a legal opinion." (quotations omitted)). Indeed, courts routinely exclude expert testimony like Dr. Najafi's where it pertains to the meaning of statutory provisions because such opinions usurp the roles of the judge and the jury. *See United States v. Barile*, 286 F.3d 749, 761 (4th Cir. 2002) (refusing to allow expert testimony regarding the meaning of "materially misleading statements" in a submission to FDA because that phrase "has a specialized legal meaning"); *Burkhart v. Washington Metro. Area Transit Auth.*, 112 F.3d 1207, 1212 (D.C. Cir. 1997) (precluding expert testimony regarding legal term of art in ADA); *Torres v. County of Oakland*, 758 F.2d 147, 151 (6th Cir. 1985) (district court should have excluded expert testimony regarding statutory language where "the terms used by the witness have a separate, distinct and specialized meaning in the law different from that

present in the vernacular"); *United States v. Xue*, No. CR 18-122, 2022 WL 1027634, at *12 (E.D. Pa. Apr. 6, 2022) (noting that courts have "precluded witnesses from using terms with a specialized legal meaning that is more precise than the lay understanding of the term" and excluding expert testimony regarding alleged violation of statute because "the term 'trade secret' is a term of art with specialized legal meaning"); *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, No. 2:18-CV-01509, 2021 WL 3286439, at *2 (S.D. Ohio Aug. 1, 2021) ("[N]o expert may assert that a device is misbranded or misleading under the Food, Drug, and Cosmetic Act and FDA regulations because these are legal conclusions."); *Tsao v. Ferring Pharms., Inc.*, No. 4:16-CV-01724, 2018 WL 3649714, at *13 (S.D. Tex. Apr. 19, 2018) (excluding expert's opinion on misbranding under FDCA because "[t]he Federal Rules of Evidence do not permit an expert to render conclusions of law, because such testimony cannot properly assist the jury in understanding the evidence or determining a fact in issue").

Because Dr. Najafi's chemical equivalence standard has no basis in either law or industry practice, his opinion is irrelevant, unreliable, and should be excluded.

B. There Is Evidence that the RLDs Contained NDMA.

Dr. Najafi's novel "sameness" opinions suffer from an additional fatal flaw—they are based on assumptions that are not supported by the facts in the record. The key assumption that underpins Dr. Najafi's sameness opinion is that the RLDs

manufactured by Novartis, Diovan and Exforge, did not contain NDMA, or any other nitrosamine. In support of this assumption, Dr. Najafi relies solely on testing performed by Health Canada on Novartis's non-US Diovan, which his lab never validated. Najafi Dep. 222:19-21. According to Dr. Najafi, if there was evidence that the RLDs contained NDMA, it would undermine this assumption. *Id.* 148:19-24. Thanks in part to Dr. Najafi and his laboratory, such evidence exists, eviscerating the foundation of his opinion.

On June 13, 2019, a citizen petition was submitted to FDA by Valisure LLC. *See* Valisure Cit. Pet. The Valisure citizen petition requested that FDA order a recall of VCDs due to the presence of an allegedly carcinogenic solvent, N,N-Dimethylformamide ("DMF"). *Id.* Notably, the citizen petition contained the results of laboratory testing performed by Valisure on various manufacturers' valsartan-containing medications, including Novartis's RLD product, as well as VCDs manufactured by some of the Defendants in this litigation. *Id.* **This testing indicated detectable levels of NDMA in the RLDs**. *Id.*

Specifically, with respect to Novartis, the citizen petition reflects testing performed on its 40 mg valsartan tablets (i.e., Diovan) and 320/12.5 mg valsartan/HCTZ tablets (i.e., Diovan HCT). *Id.* Although Dr. Najafi assumes, for purposes of his litigation opinion, that Novartis's product did not contain nitrosamines, the citizen petition showed detectable levels of NDMA in the majority

of Novartis product tested, including a level of 17 nanograms in a 40 mg tablet. *Id.* This evidence invalidates Dr. Najafi's key assumption.

There can be no question that the Novartis product tested by Valisure in connection with the citizen petition was the RLD, marketed and sold by Novartis in the United States. Notably, Novartis does not hold an ANDA for either generic valsartan or generic valsartan/HCTZ.[4] Nor does Novartis manufacture an authorized generic form of Diovan, Exforge, or the other RLDs. Moreover, any suggestion that Valisure was testing Novartis's product from a non-US market is refuted by the fact that Valisure requested FDA to order a recall of certain VCDs in the United States due to the presence of impurities. Testing performed on product manufactured for a foreign market would obviously not support Valisure's request. Likewise, the fact that Novartis may have been sourcing API from multiple vendors who may have utilized different manufacturing processes resulting in different impurity profiles is not surprising. Despite Plaintiffs' unfounded assertions, there is no special "Novartis process" that must always be utilized in order for Novartis to manufacture the RLD. It is commonplace for NDA holders, like Novartis, to purchase API and other ingredients from multiple suppliers, all of whom might employ different manufacturing processes. *See* Ex. H, Dep. of Eric Sheinin ("Sheinin Dep."), 276:4–

[4] *See* FDA Listing of Authorized Generics, available at https://www.fda.gov/media/77725/download (last accessed Apr. 15, 2022).

278:22, March 21, 2022. Indeed, Novartis amended its NDA as recently as July 2021 to add a new API supplier for Diovan.[5]

Further, Dr. Najafi cannot seriously assert that Valisure's test results are not reliable evidence because Dr. Najafi's own lab, Emery Pharma, performed validation testing for Valisure related to the citizen petition. Dr. Najafi testified unequivocally that he was able to confirm the data published in the citizen petition through independently validated testing methods performed on the exact same tablets that were analyzed by Valisure. Najafi Dep. 141:17-142:2 (stating with "[o]ne hundred percent certainty" that Emery validated the testing performed by Valisure in connection with the citizen petition). Although he later tried to retract this testimony when he realized the detrimental effect of Valisure's testing on his opinions in this case, *id.* 223:7-22, Plaintiffs do not dispute that Dr. Najafi and his lab performed testing in connection with the citizen petition. Rather, Plaintiffs claim that Dr. Najafi has no way to identify which manufacturer's valsartan he tested. *See* Ex. I, Letter from D. Nigh, March 29, 2022. This hardly matters. Even if Dr. Najafi did not specifically test the Novartis product that contained NDMA, the fact remains that he corroborated some portions of Valisure's data, which indicates he believes that Valisure's testing methods, including testing of Novartis's brand-name RLD,

[5] *See* FDA Letter, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/021283Orig1s059ltr.pdf (last accessed Apr. 15, 2022).

were sound:

> Q. So there is no question in your mind that the results of testing as documented by Valisure and its findings on nitrosamine contents in valsartan were accurate?
>
> A. **We repeated Valisure's work according to our own procedures and we, I think we – the result what we told Valisure was that the numbers they got was pretty much in the ballpark**.
>
> * * *
>
> Q. … My question was, did you have the opportunity and did in fact independently corroborate the Valisure data as it related to valsartan nitrosamine quantification?
>
> A. **That's correct. We corroborated their data**.

Najafi Dep. 142-3:10; 143:4-11 (emphasis added).

In sum, the citizen petition corroborated by Dr. Najafi's own lab constitutes evidence that NDMA was present in Novartis's brand-name RLD, which directly contradicts the core assumptions underlying Dr. Najafi's invented "sameness" opinion. Because that core assumption is invalid, Dr. Najafi's entire methodology, and his conclusion that Defendants' VCDs were not the same as the RLDs because they contained NDMA or NDEA, should be rejected as unreliable and excluded.

II. DR. NAJAFI'S LIABILITY OPINIONS ARE NOT GERMANE TO CLASS CERTIFICATION.

Dr. Najafi's remaining opinions concern liability issues, which have no bearing on class certification and on which he is not qualified to opine. Accordingly,

these opinions should also be excluded.

Dr. Najafi purports to offer the opinion that "NDMA and NDEA are carcinogenic and should not be present in any drugs." Najafi Rep. ¶ 30. Dr. Najafi is profoundly unqualified to offer any opinion regarding the carcinogenicity of NDMA or NDEA, and he performs no analysis to support his bald conclusion. As explained above, however, Dr. Najafi is not a medical doctor, a toxicologist or an epidemiologist, and has never conducted any peer-reviewed research on the carcinogenicity of NDMA. *Id.* 106:5-106:18; *see also id.* 161:2-5 (testifying that "I haven't published on [drug safety and cancer risk] . . . That's really a toxicologist and epidemiologist sort of activity. I rely on them."). In fact, Dr. Najafi conceded at his deposition that he is not offering any opinion on whether exposure to NDEA or NDMA did or can cause cancer in humans. *Id.* 107:11-107:13. Further, unlike Plaintiffs' and Defendants' general causation experts, there is no indication that Dr. Najafi systematically reviewed the scientific literature regarding the carcinogenicity of NDMA or NDEA. Without performing such an assessment of the evidence, Dr. Najafi cannot be permitted to offer an unsupported conclusion. And, in any event, this opinion does not "fit" because it is not ultimately relevant to class certification.

Likewise, Dr. Najafi's opinions that NDMA and NDEA "should not be present" in Defendants' VCDs and that "Defendants had an obligation to manufacture their products in such a way . . . that their Valsartan containing products

did not contain NDMA or NDEA" are liability issues that will, presumably, be addressed only if this Court certifies one of more of Plaintiffs' putative classes. Najafi Rep. ¶¶ 30, 31. Putting aside the substance of Dr. Najafi's liability opinions—which Defendants dispute—these opinions do not satisfy Rule 702's "fit" requirement because they are not relevant to the particular issues that are germane to class certification. *See U.S. v. Ford*, 481 F.3d at 220 n.6 ("[V]alidity for one purpose is not necessarily validity for other unrelated purposes.") (citations omitted).

In any event, as discussed *supra*, even if these liability issues were relevant to class certification—and they are not—Dr. Najafi should not be permitted to offer what are, effectively, legal conclusions regarding generic manufacturers' obligations in the guise of expert testimony. *Berckeley Inv. Grp.*, 455 F.3d at 217; *Barile*, 286 F.3d at 761; *Burkhart*, 112 F.3d at 1212; *Xue*, 2022 WL 1027634, at *12; *In re Davol, Inc./C.R. Bard, Inc., Polypropyl-ene Hernia Mesh Prod. Liab. Litig.*, 2021 WL 3286439, at *2; *Tsao*, 2018 WL 3649714, at *13. For this reason, too, Dr. Najafi's improper liability opinions should be excluded.

CONCLUSION

For the foregoing reasons, Dr. Najafi's class certification opinions should be excluded.

Dated: May 3, 2022

Respectfully Submitted:

By: */s/ Clem. C. Trischler*

Clem C. Trischler
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CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2022, a copy of the foregoing document was served on all counsel of record via CM/ECF.

By: */s/ Clem C. Trischler*
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